



Docket No.: G0365.0365/P0365
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Gregory Gregoriadis

Application No.: 10/617,734

Confirmation No.: 3606

Filed: July 14, 2003

Art Unit: 1614

For: LIPOSOMES

Examiner: Not Yet Assigned

INFORMATION DISCLOSURE STATEMENT (IDS)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR 1.56, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

Timing of Filing of the Information Disclosure Statement:

- ☒ This IDS is being filed before the First Office Action¹.
- ☐ This IDS is being filed after the issuance of the First Office Action but before the issuance of a Final Office Action².

¹ The IDS should, where possible, include a certification under 37 C.F.R. §1.97(e).

² The IDS *must* include *either* a certification under 37 C.F.R. §1.97(e) *or* the fee set forth in 37 C.F.R. §1.17(p).

- ☐ This IDS is being filed after the issuance of a Final Office Action but before the payment of the Final Fee³.

Certifications:

If checked, the undersigned makes the following statement(s):

- ☐ Statement under 37 CFR § 1.97(e):

Each item of information contained in this information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this information disclosure statement; or

No item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in this information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.

- ☐ Statement Under 37 C.F.R. § 1.704(d):

Each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in §1.56(c) more than thirty days prior to the filing of this information disclosure statement.

Fee Required by 37 C.F.R. § 1.97(c)(2) or 1.97(d)(2):

- ☐ If checked, the fee of \$180.00 set forth in 37 C.F.R. §1.17(p) is attached.

³ The IDS *must* include *both* a certification under 37 C.F.R. §1.97(e) *and* the fee set forth in 37 C.F.R. §1.17(p).

Copies of Information:

In accordance with 37 C.F.R. §1.98(a), the following are enclosed:

- ☒ A legible copy⁴ of each document (or relevant portion thereof) is cited in the attached PTO/SB/08.
- ☒ With respect to any information which is not in English, a concise explanation of the relevance, as it is presently understood by the individual designated in § 1.56(c) most knowledgeable about the content of the information, is attached. This concise explanation is provided by way of:
 - ☐ A translation of the relevant portions of the non-English language information⁵;
 - ☐ A statement explaining the relevant portions of the non-English language information;
 - ☐ A copy [and, where not in the English language, a translation] of at least the relevant portion(s)⁶ of the communication from a foreign patent office in a counterpart foreign application in which the information was cited; or
 - ☐ This information is contained in the specification of the present application.

⁴ A legible copy of the document is not required if (1) the information was previously cited by, or submitted to, the Office and considered by the Office in a prior U.S. application to which this application claims priority, provided that the prior application is properly identified in this IDS, and (2) the IDS submitted in the earlier application complies with 37 C.F.R. § 1.98(a) – (c). This exception does not apply to information cited in an International Application.

⁵ 37 C.F.R. §1.98(a)(3)(ii) *requires* that an English language translation be provided when a translation of the document, or portion thereof, “is within the possession, custody or control of, or is readily available to any individual designated in 37 C.F.R. § 1.56(c).”

⁶ The relevant portion is that portion which indicates the degree of relevance found by the foreign patent office. This may be an explanation of which portion of the of the reference is particularly relevant, to which claims it applies, or merely an “X”, “Y”, or “A” indication on a search report. MPEP §609 III A(3).

☒ In accordance with 37 C.F.R. 1.98(d), copies of the cited documents are not enclosed as they were provided in application Serial No. 09/254,695, filed May 14, 1999, which the present application relies upon for an earlier effective filing date under 35 U.S.C. 120.

Materiality:

Whether or not the information and references disclosed in this Information Disclosure Statement is "material" pursuant to 37 CFR 1.56, this submission is not intended to constitute an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

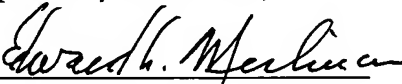
In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists.

It is submitted that the Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

In the event the actual fee is inadvertently not enclosed or if any additional fee during the prosecution of this application is not paid, the Patent Office is authorized to charge the underpayment to Deposit Account No. 50-2215.

Dated: December 11, 2003

Respectfully submitted,

By 

Edward A. Meilman

Registration No.: 24,735

DICKSTEIN SHAPIRO MORIN &
OSHINSKY LLP

1177 Avenue of the Americas, 41st Floor
New York, NY 10036-2714
(212) 835-1400



PTO/SB/08a/b (08-03)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>			Complete if Known		
			Application Number	10/617,734-Conf. #3606	
			Filing Date	July 14, 2003	
			First Named Inventor	Gregory Gregoriadis	
			Art Unit	1614	
			Examiner Name	Not Yet Assigned	
Sheet	1	of	4	Attorney Docket Number	G0365.0365/P0365

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	AA	US-4,897,355	01/30/1990	Eppstein et al.	
	AB	US-4,515,736	05/07/1985	Deamer	
	AC	US-5,567,433	10/22/1996	Collins	
	AD	US-5,661,025	08/26/1997	Szoka Jr. et al.	
	AE	US-5,830,878	11/03/1998	Gorman et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
	BA	WO 91/17424		11/14/1991		
	BB	EP 0475178		03/18/1992		
	BC	JP 2-135092		05/23/1990		
	BD	JP 1-047381		02/21/1989		
	BE	WO 95/04524		02/16/1995		
	BF	WO 95/13796		05/26/1995		

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	CA	P.L. FELGNER, ET AL., "Nomenclature for Synthetic Gene Delivery Systems", Human Gene Therapy, 8:511-512, March 20, 1997	
	CB	CHRISTOPHER KIRBY, ET AL., "Dehydration-Rehydration Vesicles: A Simpl Method for High Yield Drug Entrapment in Liposomes", Research Paper: Academic Department of Medicine, Royal Free Hospital School of Medicine, University of London, Biotechnology, November 1984, pp. 979-984	
	CC*	Y. PERRIE, ET AL., "Liposome Entrapped Plasmid DNA: Characterisation Studies" Biochim. Biophys. Acta 1475 (2000) , pp. 125-132	
	CD*	G. GREGORIADIS, ET AL., "Liposomes Mediated DNA Vaccination", FEBS Letters 402 (1997), pp. 107-110	
	CE*	A. BACON, ET AL., "Induction of a Cytotoxic T Lymphocyte (CTL) Response to Plasmid DNA Delivered Via Lipodine Liposomes," Journal of Liposome Research, 12 (1&2), (2002), pp. 173-183	
	CF*	Y. PERRIE, ET AL., "Liposome Mediated DNA Vaccination: The effect of vesicle composition" Vaccine 19 (2001), pp. 3301-3310	



PTO/SB/08a/b (08-03)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application Number	10/617,734-Conf. #3606
				Filing Date	July 14, 2003
				First Named Inventor	Gregory Gregoriadis
				Art Unit	1614
				Examiner Name	Not Yet Assigned
Sheet	2	of	4	Attorney Docket Number	G0365.0365/P0365

	CG*	G. GREGORIADIS, "Drug and Vaccine Delivery Systems," In: PharmaTech 2001, World Markets Research Centre Ltd., (2001), pp. 172-176	
	CH*	G. GREGORIADIS, "Genetic Vaccines: Strategies for Optimization", Pharmaceutical Research Vol. 15, No. 5 (1998), pp. 661-670	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

*References attached. Other references cited in parent case.

APPLICANT'S ART CITATION (Use several sheets if necessary)		Application 09/254,695		OFGS File No. P/365-331	
		Applicant Gregory GREGORIADIS			
		Filing Date May 14, 1999		Group Art Unit 1651	

344
 O.T.P.E. JG17
 DEC 11 2003
 PATENT & TRADEMARK OFFICE

U.S. PATENT DOCUMENTS												
Examiner Initial	Document Number							Date	Name	Class	Sub-class	Filing Date If Appropriate
	4	9	4	6	7	8	7	8/7/90	Eppstein, et al.			
	5	0	4	9	3	8	6	9/17/99	Eppstein, et al.			
	5	2	0	8	0	3	6	5/4/93	Eppstein, et al.			
	5	3	6	6	7	3	7	11/22/94	Eppstein, et al.			
	5	4	5	9	1	2	7	10/17/95	Felgner, et al.			
	5	5	4	5	4	1	2	8/13/96	Eppstein, et al.			
	5	5	5	0	2	8	9	8/27/96	Eppstein, et al.			
	5	6	2	2	7	1	2	7/22/97	Eppstein, et al.			5/4/94

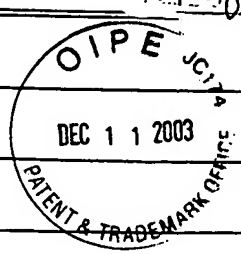
FOREIGN PATENT DOCUMENTS													
	Document Number							Date	Country	Class	Sub-class	Translation	
												Yes	No
	0	1	7	2	0	07	B1	5/22/91	EPO				
	0	1	8	7	7	02	A1	7/16/86	EPO				
	9	0/	1	1	0	9	2	10/4/90	WIPO				
	9	3/	1	4	7	7	8	8/5/93	WIPO				

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)	
	"Genetic Chemistry: Towards non-enzymatic..." in Targeting of Drugs: Strategies for Oligonucleotide and Gene Delivery in Therapy, eds Gregoriadis, G. and McCormack, B.; Behr, J-P.; 1996.
	"Immune Responses with Direct Gene Transfer: DNA Vaccines and Implications for Gene Therapy" from "Targeting of drugs..." op cit; Davis, HL; 1996.
	High Yield Incorporation of Plasmid DNA without Liposomes: Effect on DNA Integrity and Transfection Efficiency"; J. Drug Targeting (1996); 3, 469-475; Gregoriadis, G., et al.; 1995.
	IBC's second annual genetic vaccines and Immunotherapeutic Strategies conference, 1996-abstract by Felgner, et al. "Synthetic Gene Delivery Systems for Nucleic Acid Immunisation" and Ledley, FD "Gene Expression and Delivery Systems for Nucleic Acid Vaccines"; 1996.
	"Enhanced Gene Delivery and Mechanism Studies with a Novel Series of Cationic Lipid Formulations"; J. Biol. Chem. (1994) 269(4) 2550-2561; Felgner, J.H., et al.; 1994.
	"Synthetic Gene-Transfer Vectors", Acc. Chem. Res. (1993) 26, 274-278; Behr, J-P; 1993.
	"Gene Transfer with Synthetic Cationic Amphiphiles; Prospects for Gene Therapy"; Bioconjugate Chemistry (1994) 5, 382-389; Behr, J-P; 1994.

Examiner	Date Considered
----------	-----------------

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant.

APPLICANT'S ART CITATION (Use several sheets if necessary)		Application 09/254,695		OFGS File No. P/365-331	
		Applicant Gregory GREGORIADIS			
		Filing Date May 14, 1999		Group Art Unit 1651	

4064


U.S. PATENT DOCUMENTS												
Examiner Initial	Document Number							Date	Name	Class	Sub-class	Filing Date If Appropriate

FOREIGN PATENT DOCUMENTS													
	Document Number							Date	Country	Class	Sub-class	Translation	
												Yes	No

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)	
	"Mode of Formation and Structural Features of DNA-Cationic Liposome Complexes Used for Transfection"; Biochemistry (1993) 32,7143-7151; Gershon, et al.; 1993.
	"DNA-Lipid Complexes: Stability of Honeycomb-Like and Spaghetti-like Structure" Biophysical Journal (November 1997) 73, 2427-2440; May, S.; 11/1997.
	"The Structure of DNA-Liposome Complexes"; J. Am. Chem. Soc. (1997); 119, 832-833; Lasic, D.D., et al.; 1997.
	"New Structures in Complex Formation Between DNA and Cationic Liposomes Visualised by Freeze-Fraction Electron Microscopy"; FEBS Letts. (1994) 356,361-366; Sternberg, B., et al.; 1994.
	"Cationic Liposome-Mediated Transfection"; Nature (January 1989); 337, 387-388; Felgner, P.L., et al.; 1/1989.
	"Virus-Sized Self-Assembling Lamellar Complexes Between Plasmid DNA and Cationic Micelles Promote Gene Transfer"; Proc. Natl. Acad. Sci. USA (December 1997); 94, 14412-14417; Pitard, B., et al.
	"Structure of DNA Cationic Liposome Complexes: DNA Intercalation in Multilamellar Membranes in Distance Interhelical Packing Regimes"; Science (February 1997); 272, 810-814; Radler, O., et al.
	"Multilamellar Structures of DNA Complexes with Cationic Liposomes"; Biophysical Journal (October 1997); 73, 1842-1846; Dan, N.
	"Formation of Ordered Domains in Membrane-Bound DNA"; Biophysical Journal (September 1996); 71, 1267-1272; Dan, N.

Examiner	Date Considered
----------	-----------------

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant.